EXHIBIT 15

US012274554B2

(12) **United States Patent**
Kumar et al.

(10) **Patent No.: US 12,274,554 B2**
(45) **Date of Patent: *Apr. 15, 2025**

(54) **DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **18/936,888**

(22) Filed: **Nov. 4, 2024**

(65) **Prior Publication Data**

US 2025/0057459 A1 Feb. 20, 2025

Related U.S. Application Data

(63) Continuation of application No. 17/304,811, filed on Jun. 25, 2021, now Pat. No. 12,133,734, which is a

(Continued)

(51) **Int. Cl.**

A61B 5/00 (2006.01)
A61B 5/05 (2021.01)

(Continued)

(52) **U.S. Cl.**

CPC ***A61B 5/282*** (2021.01); ***A61B 5/25*** (2021.01); ***A61B 5/259*** (2021.01); ***A61B 5/291*** (2021.01);

(Continued)

(58) **Field of Classification Search**

CPC A61B 5/04; A61B 5/0408; A61B 5/04085; A61B 5/04087; A61B 5/0492;

(Continued)

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(57) **ABSTRACT**

An electronic device for long-term adhesion to a mammal includes a housing with an electronic component. The electronic device may include a first wing and a second wing, each being integrally formed with the housing. An electrode is positioned on a bottom surface of each of the wings, the electrodes electrically connected to the electronic component. An adhesive layer is provided for adhesion to a surface of the mammal. The adhesive layer may cover a portion of the bottom surfaces of the wings but generally does not cover the electrode or a bottom surface of the housing. A method of applying an electronic device to a mammal includes removing first and second adhesive covers

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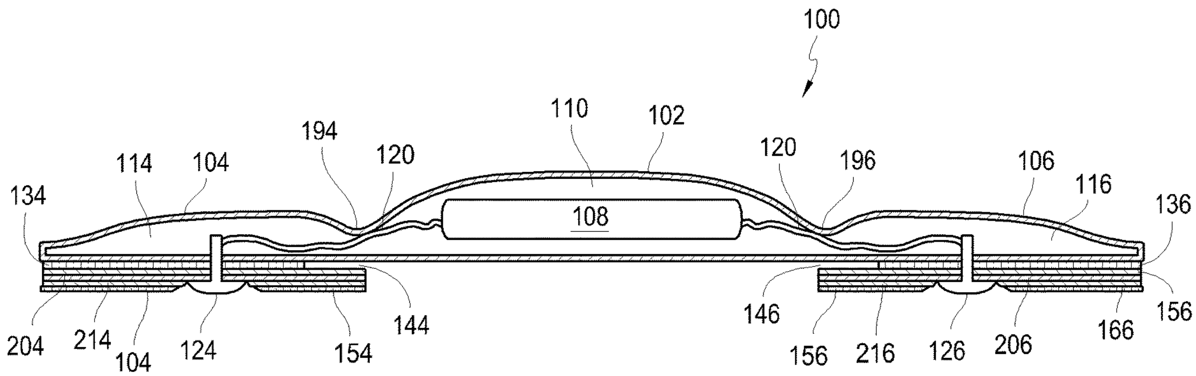

from first and second wings of the electronic device to expose an electrode and an adhesive coated on a bottom surface of each wing.

13 Claims, 11 Drawing Sheets

Related U.S. Application Data

continuation of application No. 16/723,208, filed on Dec. 20, 2019, now Pat. No. 11,141,091, which is a continuation of application No. 16/138,819, filed on Sep. 21, 2018, now Pat. No. 10,517,500, which is a continuation of application No. 15/005,854, filed on Jan. 25, 2016, now Pat. No. 10,405,799, which is a continuation of application No. 13/890,144, filed on May 8, 2013, now Pat. No. 9,241,649, which is a continuation of application No. 13/563,546, filed on Jul. 31, 2012, now Pat. No. 8,538,503, which is a continuation of application No. 13/106,750, filed on May 12, 2011, now Pat. No. 8,560,046.

(60) Provisional application No. 61/334,081, filed on May 12, 2010.

(51) **Int. Cl.**

A61B 5/25 (2021.01)
A61B 5/259 (2021.01)
A61B 5/282 (2021.01)
A61B 5/291 (2021.01)
A61B 5/389 (2021.01)

(52) **U.S. Cl.**

CPC ***A61B 5/6832*** (2013.01); ***A61B 5/6833*** (2013.01); ***A61B 5/68335*** (2017.08); *A61B 5/389* (2021.01); *A61B 2560/0406* (2013.01); *A61B 2560/0468* (2013.01); *Y10T 156/10* (2015.01)

(58) **Field of Classification Search**

CPC A61B 5/0531; A61B 5/6801; A61B 5/6832–6833
USPC 600/372, 382–393
See application file for complete search history.

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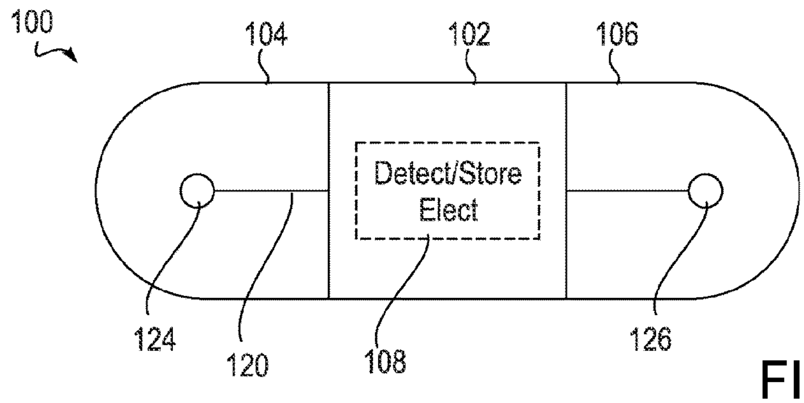
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104
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106
Detect/Store
Elect
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120
108
126

FIG. 1

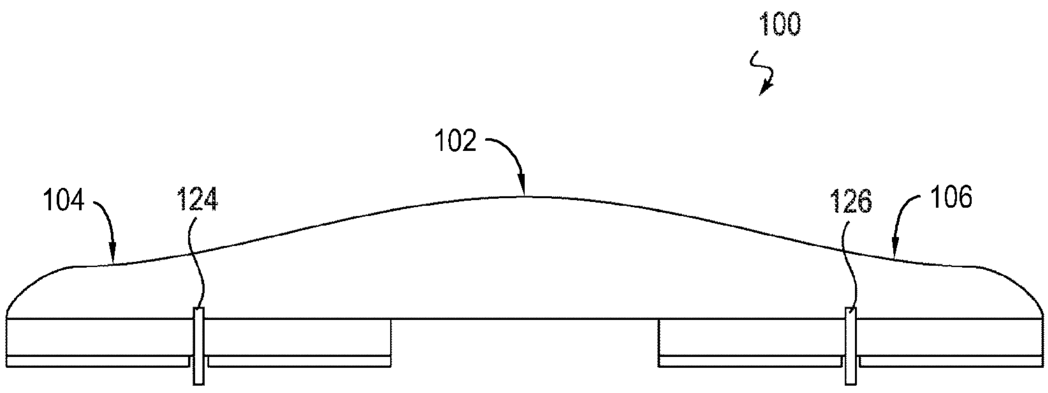
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FIG. 1A

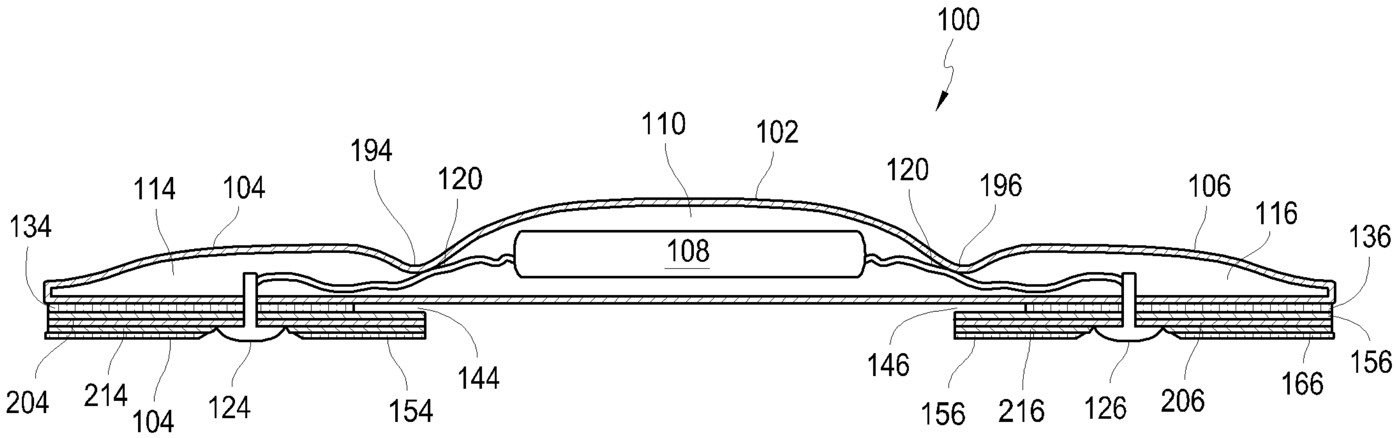
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FIG. 1B

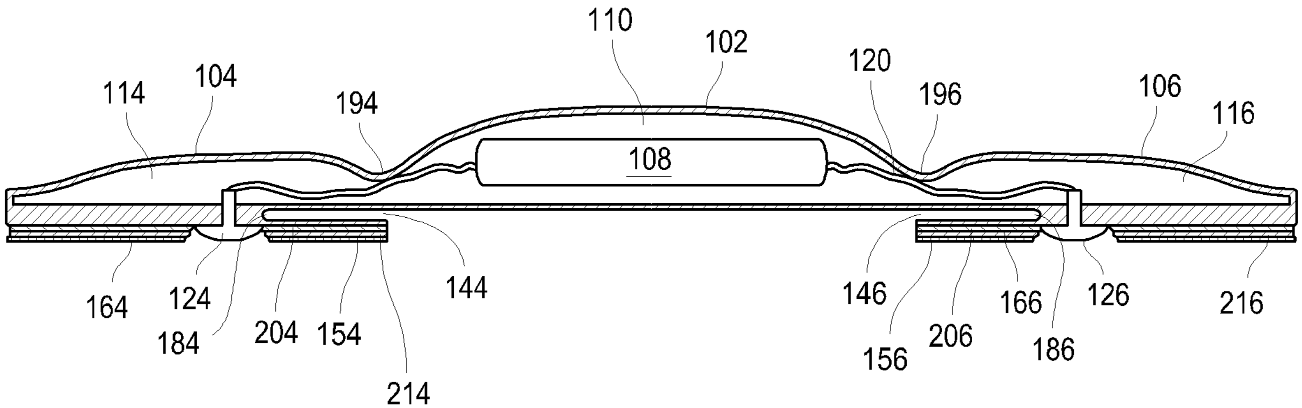
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FIG. 1C

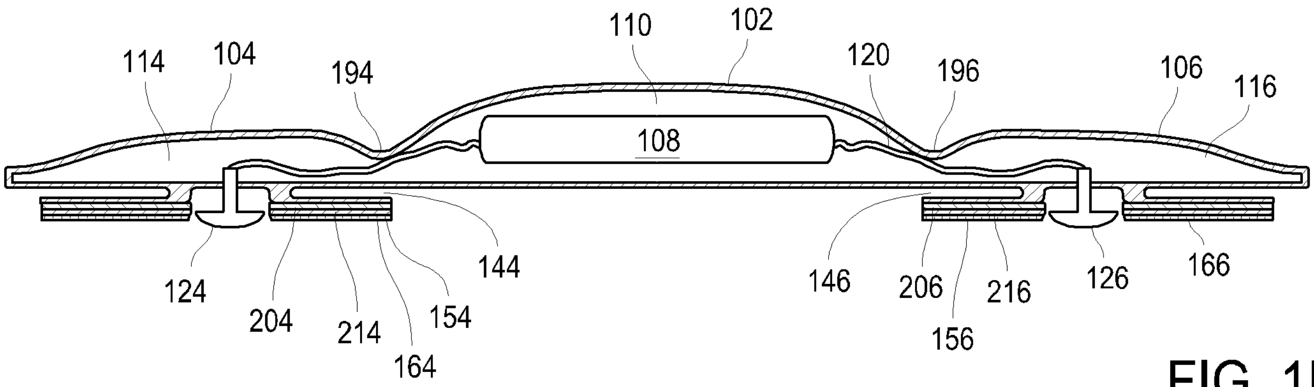

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FIG. 1D

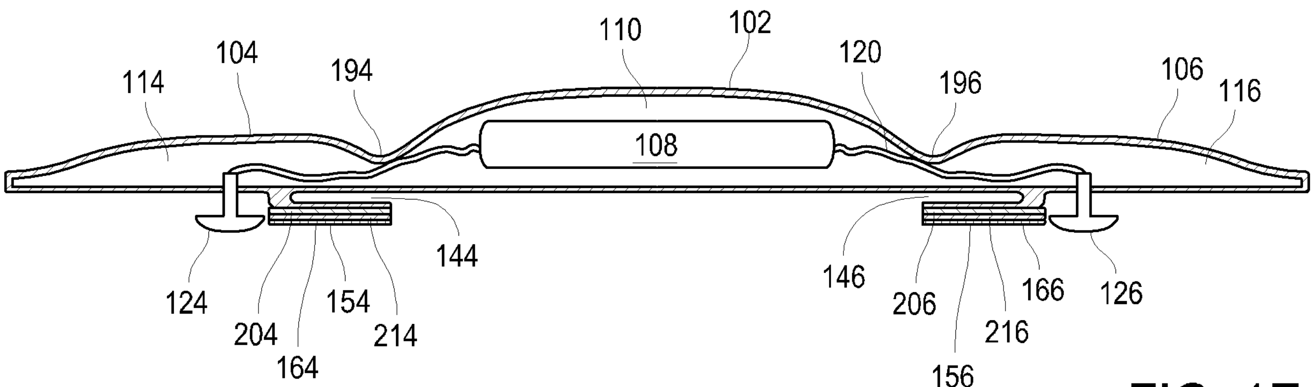

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FIG. 1E

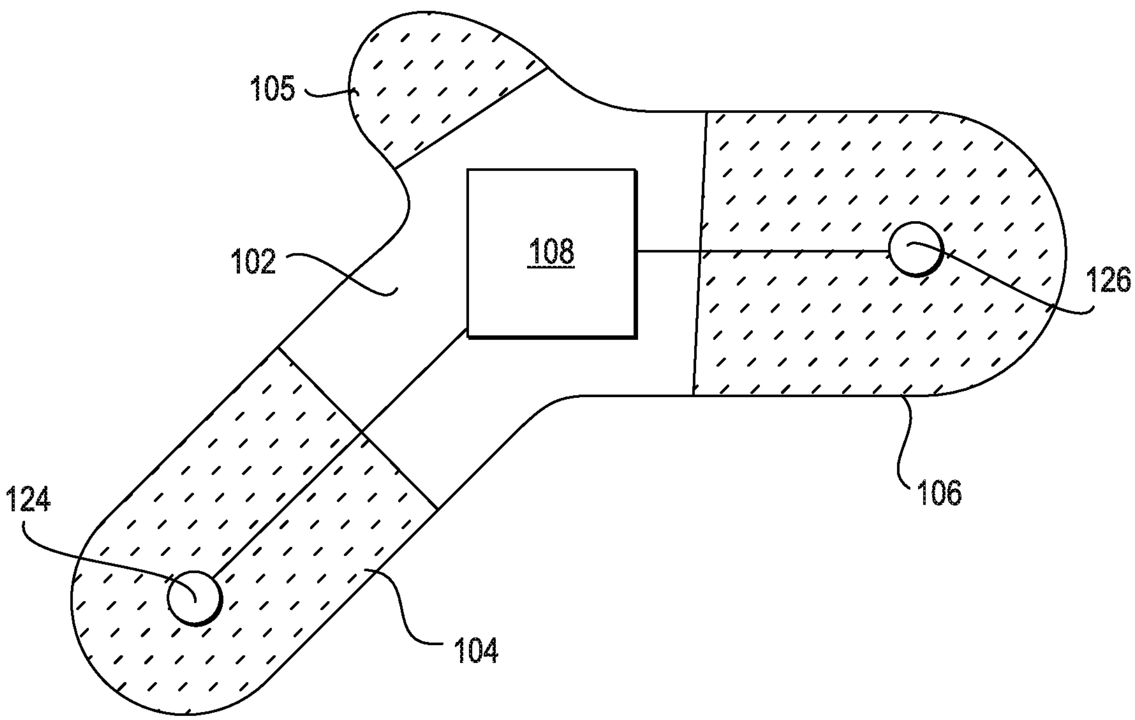

FIG. 1F

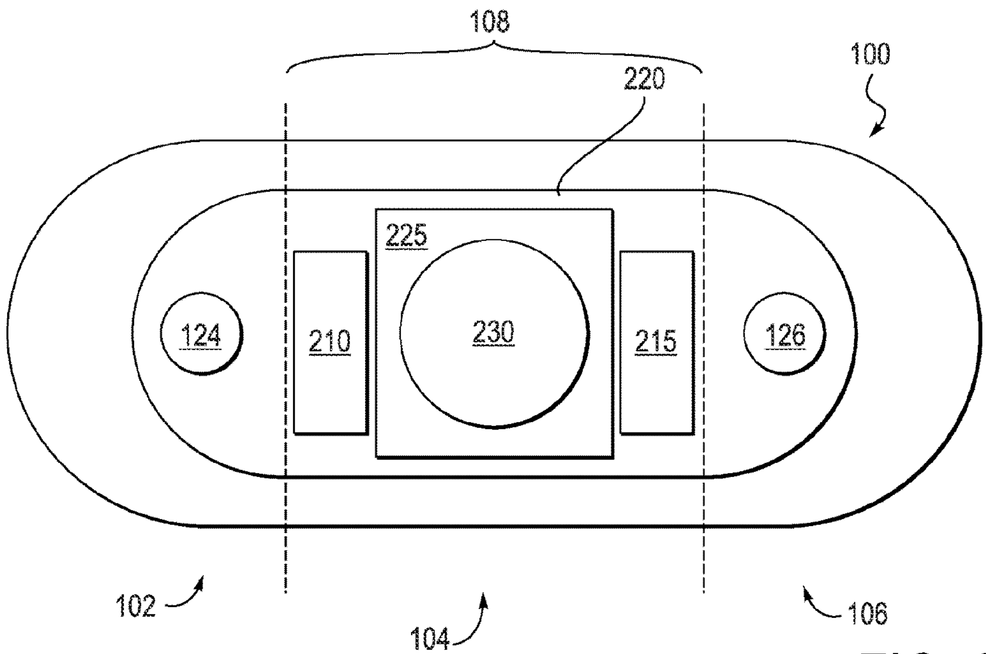

FIG. 2A

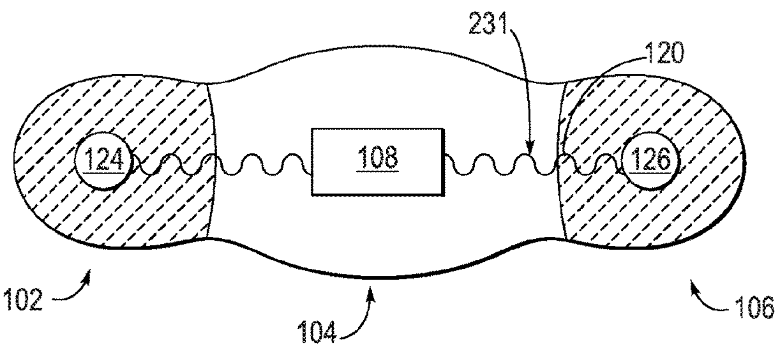

FIG. 2B

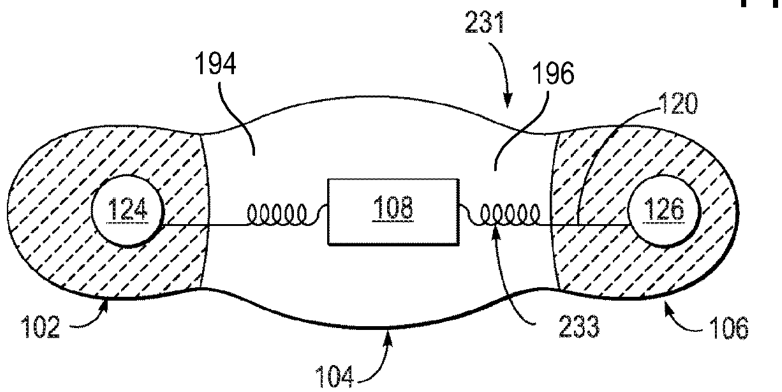

FIG. 2C

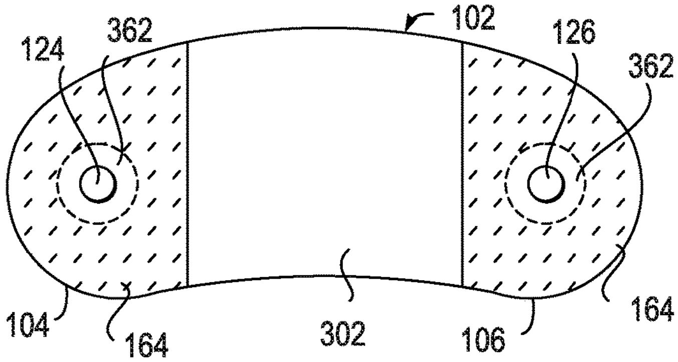

FIG. 3

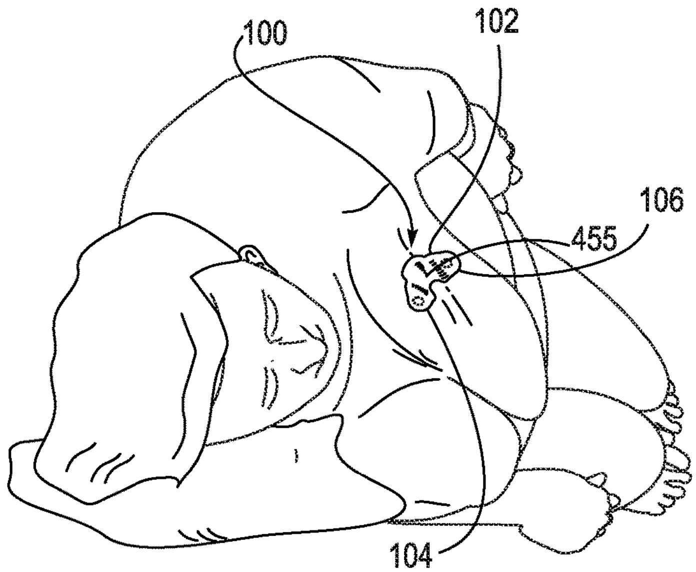

FIG. 4A

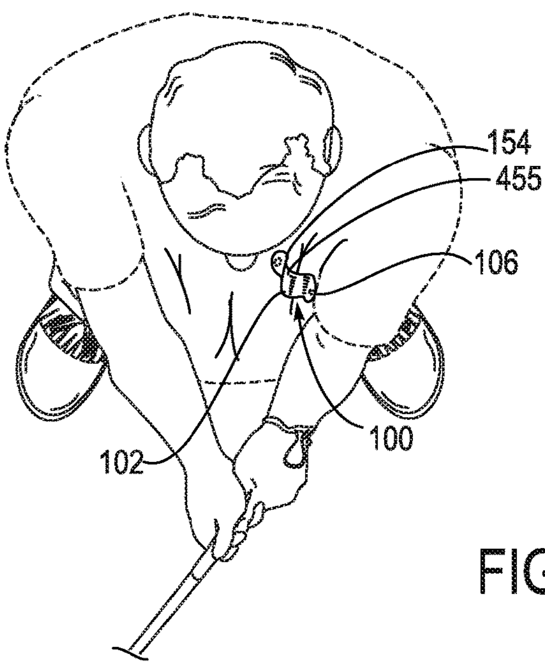

FIG. 4B

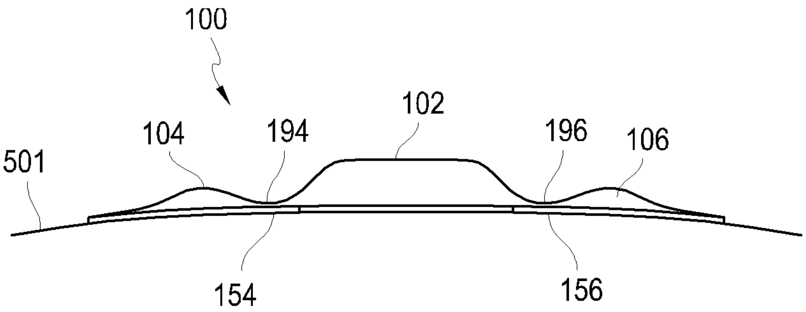

FIG. 5A

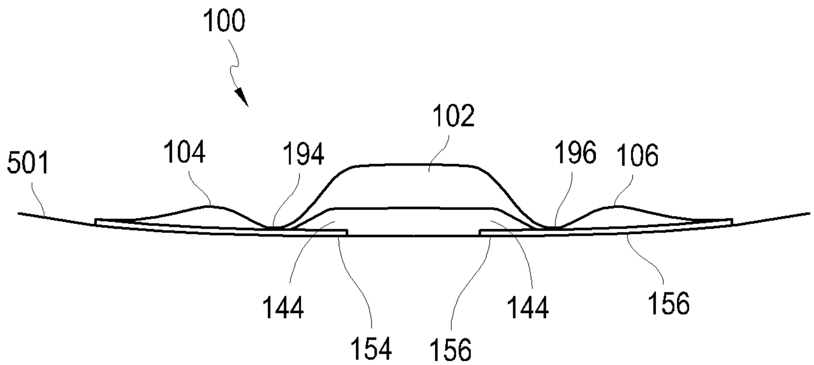

FIG. 5B

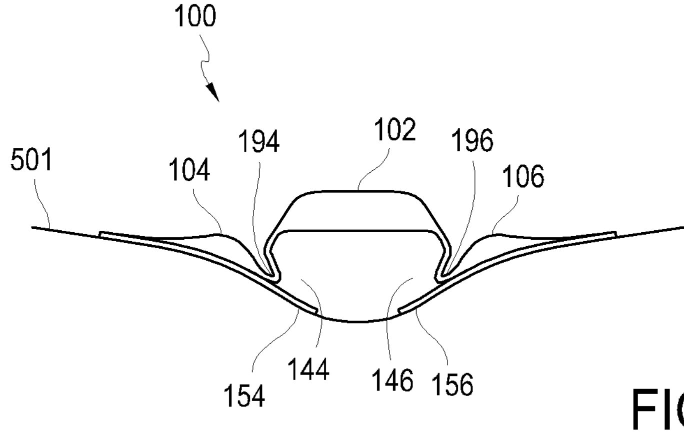

FIG. 5C

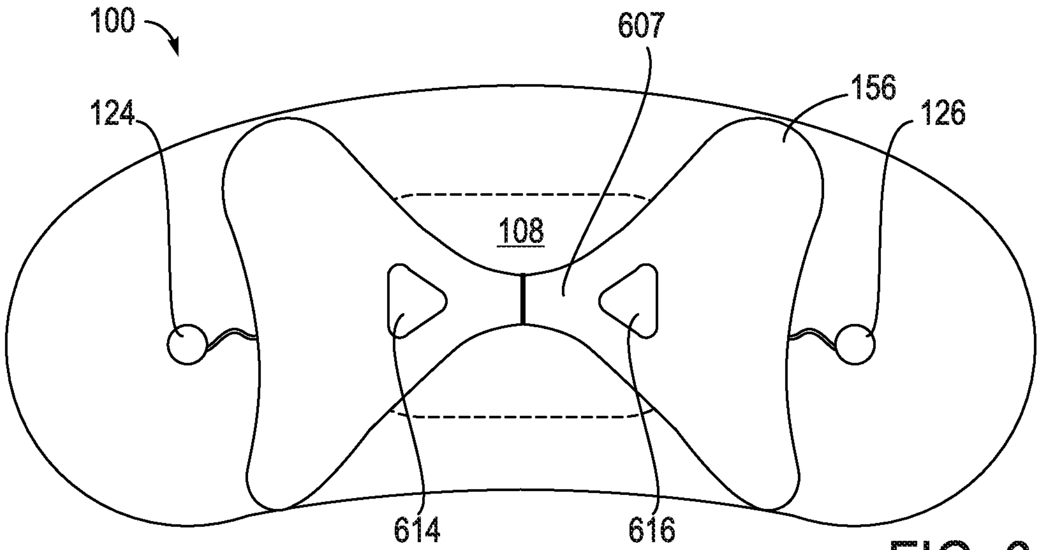

FIG. 6A

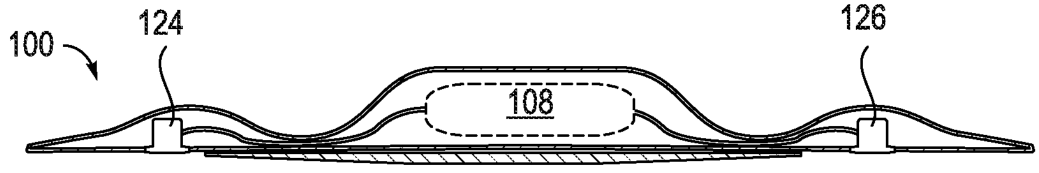

FIG. 6B

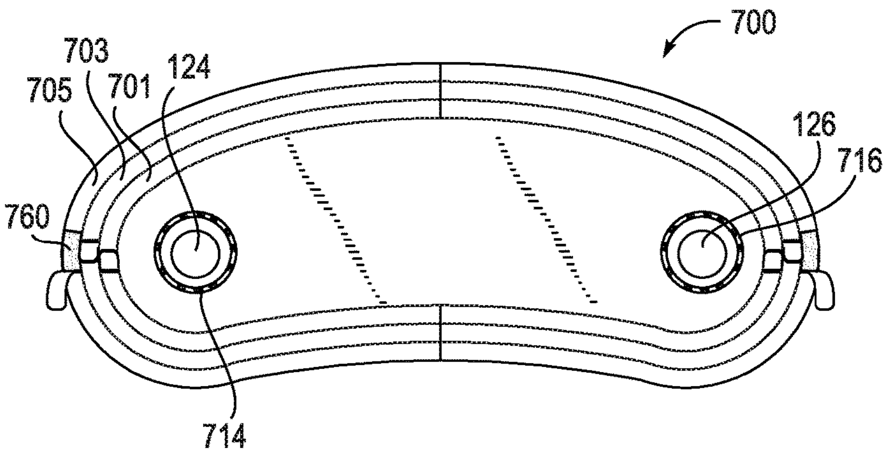

FIG. 7A

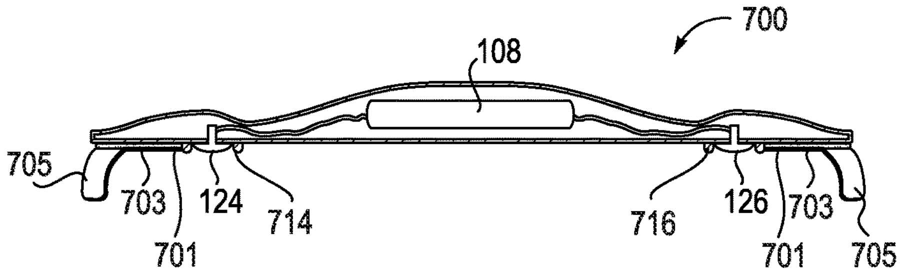

FIG. 7B

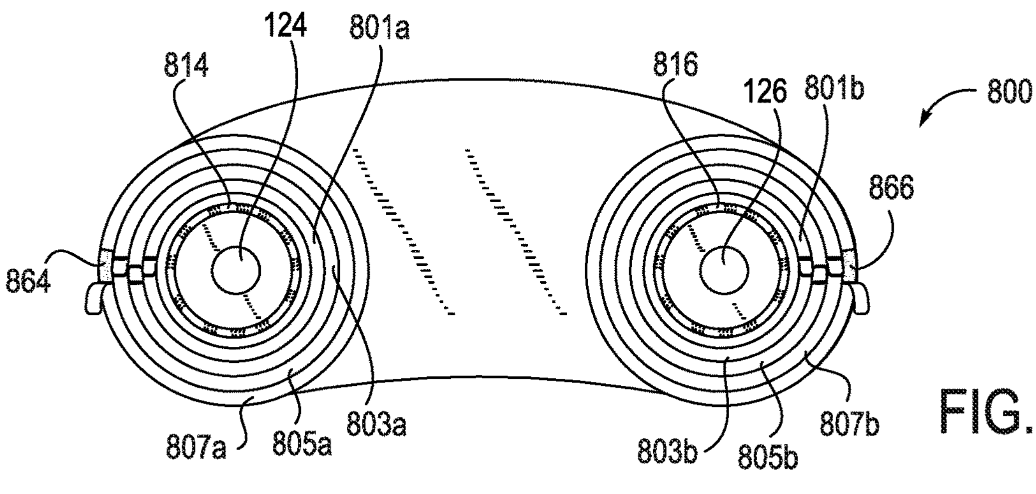

FIG. 8A

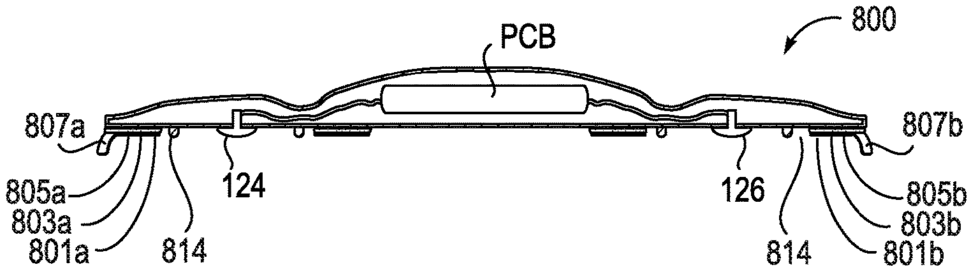

FIG. 8B

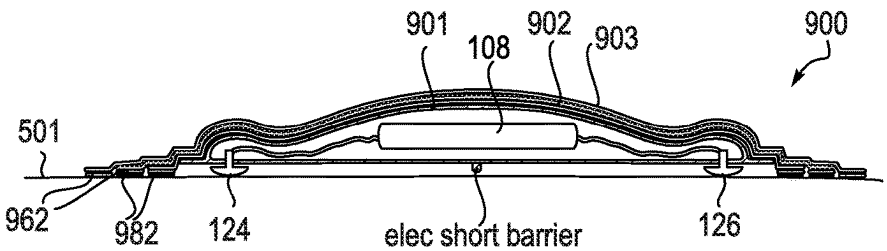

FIG. 9A

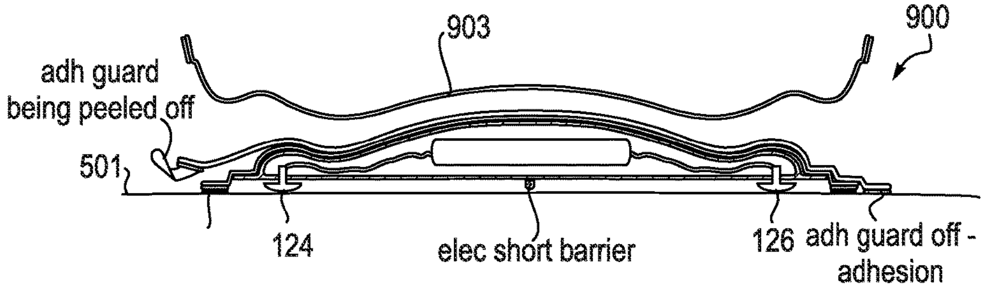

FIG. 9B

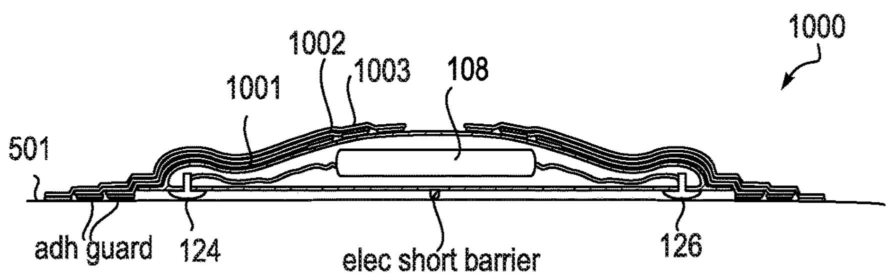

FIG. 10A

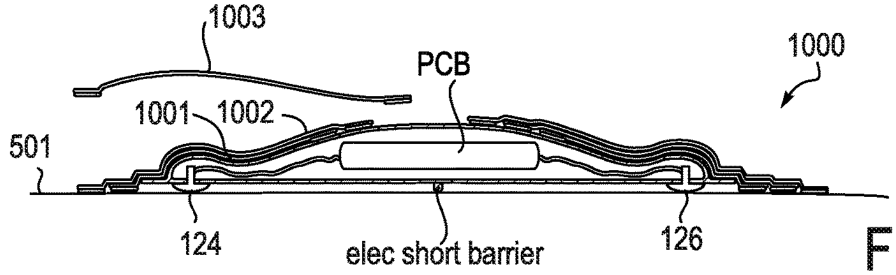

FIG. 10B

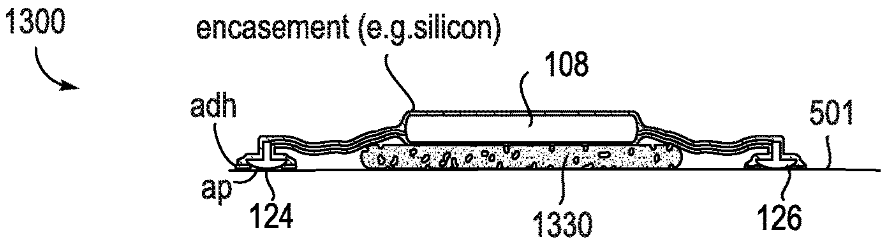

FIG. 11

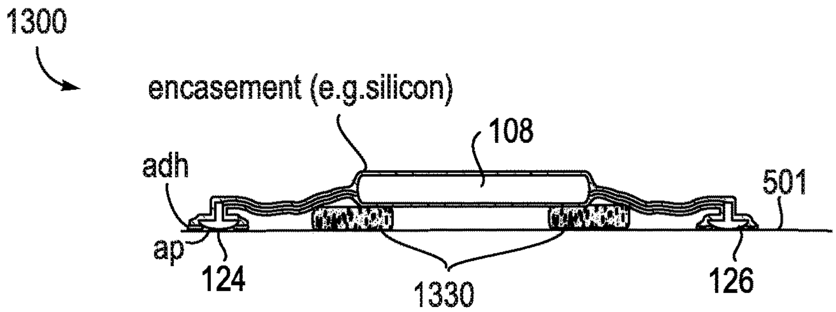

FIG. 12

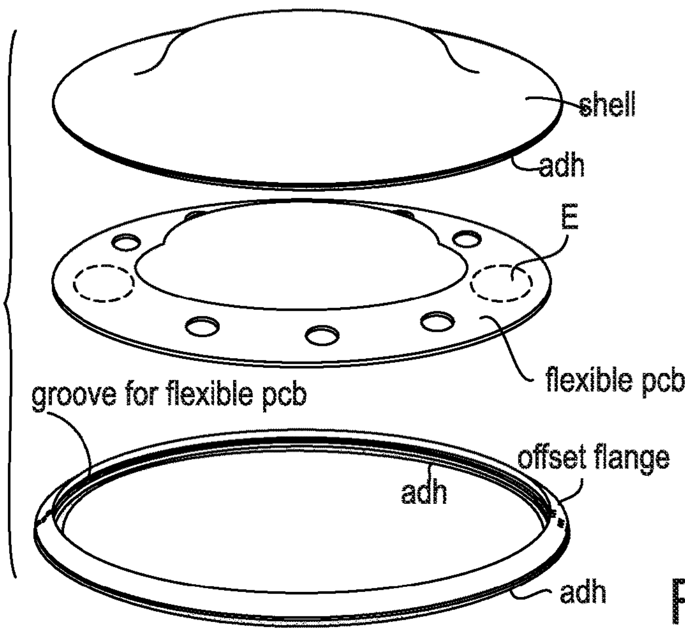

FIG. 13A

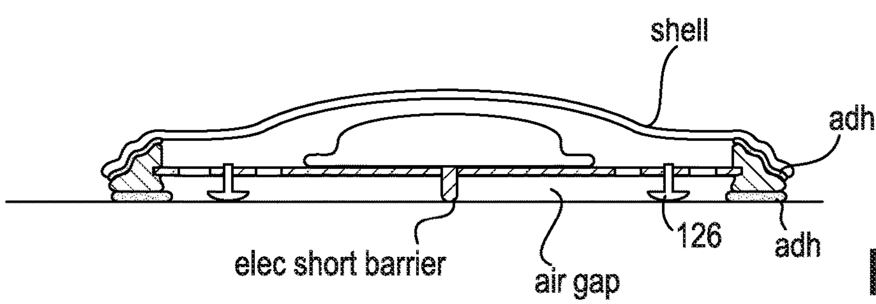

FIG. 13B

DEVICE FEATURES AND DESIGN ELEMENTS FOR LONG-TERM ADHESION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 17/304,811, filed Jun. 25, 2021, titled "Device Features And Design Elements For Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/723,208, filed Dec. 20, 2019, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 16/138,819, filed Sep. 21, 2018, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 15/005,854, filed Jan. 25, 2016, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/890,144, filed May 8, 2013, titled "Device Features and Design Elements for Long-Term Adhesion" which claims priority to U.S. application Ser. No. 13/563,546, filed Jul. 31, 2012, titled "Device Features and Design Elements for Long-Term Adhesion", which claims priority to U.S. patent application Ser. No. 13/106,750, filed May 12, 2011, which claims priority to U.S. Provisional Patent Application No. 61/334,081, filed May 12, 2010, entitled "Device Features and Design Elements for Long-Term Adhesion." All of the aforementioned applications are incorporated by reference as if fully set forth herein.

INCORPORATION BY REFERENCE

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD OF THE INVENTION

This application relates to devices worn on a body for monitoring, recording, reporting and/or treating the person wearing the device. Improvements in the device design elements and functionality are disclosed for maintaining the device in contact with and operational for extended periods of time, typically longer than 24 hours.

BACKGROUND OF THE INVENTION

The ability to adhere a medical device to a human body for a long-period of time is dependent on a variety of factors. In addition to the type and nature of the adhesive chosen, another factor is the mechanical design of the device. By design, this refers to, but is not limited to, the device shape, size, weight, flexibility, and rigidity. These design elements are influenced by a number of additional factors, including, hut not limited to, where on the body the device will attach and the duration of the attachment, moisture conditions in that area, movement conditions in that area, stretching and contraction in that area, interactions with external factors in that area such as clothing, and purposeful and/or inadvertent interaction between the person wearing the device and the device.

As many are typically used on the body for less than 24 hours, devices have not been designed that can withstand longer-term adhesion. Hence, there is a need to implement device features and design elements that have the ability to

enhance the likelihood of adhesion of a device to a human body for 24 hours or more, while accommodating the functionality, shape, size, weight, flexibility, and rigidity of a given device.

SUMMARY

In one aspect of the invention, there is an electronic device for long-term adhesion to a mammal. The device has a housing containing an electronic component with a first wing and a second wing integrally formed with the housing. There is an electrode positioned on a bottom surface of each of the wings with the electrodes electrically connected to the electronic component. An adhesive layer is provided tor adhesion to a surface of the mammal. The adhesive layer is coated on a portion of the bottom surface of the wings. The adhesive layer is not coated on the electrode or on a bottom surface of the housing.

The electronic component in any of the devices described herein may include a processor having a memory with computer readable instructions to record signals from the first and second electrodes while the electronic device is attached to the mammal. The processor may be configured to only convert signals from the electrodes to digital signals, filter those signals and then store the signals in memory.

In another aspect, the device includes a flap connected to each of the wings. The flaps may extend below the housing. Additionally or alternatively, the adhesive layer is coated on a bottom surface of the flaps.

In another aspect, the device includes a connector segment In one aspect, the connector segment configured to connect the flaps together. In other aspects, the connector segment is located at least partially below the housing. Still further, the connector segment is not attached to the housing.

In one alternative, the adhesive layer is coated on a bottom surface of the flap.

In still another aspect, the adhesive for adhesion to a surface of the mammal is an adhesive that can absorb fluids. In another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In another aspect, the adhesive for adhesion to a surface of the mammal is a pressure-sensitive adhesive. The pressure sensitive adhesive is selected from the group consisting of: a polyacrylate, a polyisobutylene, and a polysiloxane. In one alternative, the device includes a diffusion barrier between the adhesive layer and each of the wings. The device may also include an additional adhesive layer and material layer between the wing and the adhesive layer for adhesion to the mammal. The material layer is configured to prevent diffusion of adhesive components from the adhesive layer to the wing. The diffusion barrier may be made from polyester or other suitable synthetic material.

In one aspect of the device, all or substantially all of the electronic components are within the housing. In another aspect, the wing is free from electronic components. In one aspect, the wing is more flexible than the housing. In one alternative, the wings and the housing are made from the same material. In another aspect, the wings and the housing are made from different materials. In another, the wings are made from a fabric. In still another aspect, the material used to make the wings includes a synthetic fiber. In another alternative, the wing and the flap are composed of the same material.

In another alternative, the device includes a hinge portion between the housing wmg, The hinge portion is configured to allow the device to bend between the housing and the wmg. In one aspect, the hinge portion exists between a rigid

portion of the device and a flexible portion of the device. In one alternative, the rigid portion of the device corresponds to the portion of the housing including the electronics and the flexible portion of the device includes a wmg

In one aspect, the bottom surface of the wing and the bottom surface of the flap are contiguous, In another aspect, the bottom surfaces of the wings, the flap, and the connectors are contiguous. In still other aspects, the flaps and the connector are contiguous.

In another aspect, the connector has at least one hole extending it. The hole may have any of a number of shapes such as circular, oval, round, or triangular.

In one aspect, the housing is thicker at a center of the housing than at edges of the housing.

In another aspect of the device, the housing is unattached to the mammal when the electrodes are in contact with the mammal.

In another alternative aspect of a device for long-term adhesion to a mammal, the device includes a housing with a first wing extending laterally from the housing and a second wing extending laterally from the housing without overlapping the first wing, There is a first electrode positioned on a bottom surface of the first wing and a second electrode positioned on a bottom surface of the second wing. An electronic memory is positioned within the housing. The electronic memory is configured to receive and store electronic signals from the first and second electrodes while the electronic device is attached to the mammal. There is also an adhesive layer on a portion of a bottom surface of the first wing and the second wing. The adhesive is not on a bottom surface of the housing. When the device is worn on the mammal, only the adhesive layer(s) are attached to the mammal.

In one aspect, the portion of the bottom surface of the first wing and the second wing does not include the first and second electrodes, In one device aspect, the first wing, the second wing, and the housing are formed from the same material. In still another, the first wing, the second wing and the housing integrally form a monolithic structure. In other aspects, an angle formed by the first wing, the second wing, and the housing is between approximately 90° and 180°, In one variation, the angle is approximately 180°, In another variation, the angle is approximately 135°.

In still other embodiments, there is a first hinged portion between the first electrode and the processor and a second hinged portion between the second electrode and the housing.

In a further aspect, at least a portion of the body uncovered is not adhered to the mammal when signals from the electrodes are being recorded in memory.

In another aspect, the device includes a first flap connected to the first wing medial to the first electrode and a second flap connected to the second wing medial to the second electrode. Each nap may extend below the housing.

The device may also include a connector segment configured to connect the flaps together. In one aspect, the connector segment is located at least partially below the housing, but is not attached to the housing.

In another aspect, there is an electronic device that has a patch including a housing containing an electronic component. There is an electrode positioned on a bottom surface of the patch, the electrode electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive strip extending around the perimeter of the first adhesive strip, In one aspect, the first adhesive cover over the first adhesive strip and a second adhesive cover over the second adhesive strip, The first and second adhesive covers may be configured to be separably removed from the first and second adhesive strips, In one alternative, the first adhesive strip extends between the first and second adhesive covers. In another alternative, the adhesive in the first and the second adhesive strips is an adhesive that can absorb fluids. In still another aspect, the adhesive that can absorb fluids is a hydrocolloid adhesive. In one alternative, the adhesive in the first and the second adhesive is a pressure-sensitive adhesive. In some aspects, the pressure-sensitive adhesive is a polyacrylate, a polyisobutylene, or a polysiloxane.

In one alternative, the second adhesive strip partially overlaps the first adhesive strip. In another aspect, the second adhesive strip is attached to a shell, the shell overlapping the first adhesive strip.

In still another alternative device for long-term adhesion to a mammal, the device includes a patch having a housing with an electronic component contained therein, There is an electrode positioned on a bottom surface of the patch, The electrode electrically connected to the electronic component There is a porous foam pad configured to be positioned between the electronic component and the mammal. In one aspect, the porous foam pad comprises a biocompatible foam material. In one variation, the porous foam pad can absorb fluids. In still another aspect, the porous foam pad is attached to the housing. In another, the porous foam pad is configured to be attached to the mammal. In another request, the porous foam pad can absorb fluids.

In one aspect of a method of applying an electronic device, there is a step of removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of a first wing, There is a step of placing the exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the first wing to the mammal. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an adhesive coated on a bottom surface of the second wing and another exposed electrode, There is also a step of placing the another exposed electrode into contact with the mammal by adhering the adhesive coated bottom of the second wing to the mammal. After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

In one alternative method of attaching a device, the electronic device includes a first nap connected to the first wing and a second flap connected to the second wing. The first and second flaps each extend below the housing. The step of removing a first adhesive cover from the first wing may also include exposing an adhesive coated on a bottom surface of the first flap. The step of removing a second adhesive cover from the second wing may also include exposing an adhesive coated on a bottom surface of the second flap.

In another alternative method of attaching a device, after performing the removing and the placing steps, the housing is held in position on the mammal using only the adhesive coated bottoms of the first wing, the second wing, the first flap and the second flap.

In an alternative aspect of a method of applying an electronic device to a mammal for long-term adhesion, the method includes removing a first adhesive cover from the first wing of the electronic device to expose an electrode and an adhesive coated on a bottom surface of the first wing. There is also a step of removing a second adhesive cover from the second wing of the electronic device to expose an

adhesive coated on a bottom surface of the second wing and another exposed electrode. There is a step of placing the exposed electrodes into contact with the mammal by adhering the adhesive coated on the bottom of the first and the second wings to the mammal, After performing the removing and the placing steps, the housing is unattached to the mammal, but is held in position on the mammal using the adhesive coated bottoms of the first and the second wings.

There is also provided a method of applying an electronic device to a mammal for long-term adhesion wherein the electronic device includes a patch. The patch includes an electronic component along with an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch and a second adhesive extending around the perimeter of the first adhesive strip. One aspect of a method of applying the device includes a step of removing an adhesive cover from the second adhesive strip of the electronic device. There is a step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode is in contact with the mammal. Then, after a period of time, removing an adhesive cover from the first adhesive strip of the electronic device. Next, there is the step of applying pressure to the first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode remains in contact with the mammal.

In another alternative method of applying an electronic device to a mammal for long-term adhesion, the electronic device includes a patch, an electronic component, and an electrode positioned on a bottom surface of the patch and electrically connected to the electronic component. There is a first adhesive strip extending around the perimeter of the patch. The method includes a step of applying pressure to a first adhesive strip to adhere the first adhesive strip to the mammal such that the electrode is in contact with the mammal. After a period of time, placing a second adhesive strip around the perimeter of the first adhesive strip. Then there is the step of applying pressure to the second adhesive strip to adhere the second adhesive strip to the mammal such that the electrode remains in contact with the mammal.

Any of the above described devices may include additional aspects. A device may also include a first wire connecting the first electrode and the processor or an electronic memory and a second wire connecting the second electrode and the processor or an electronic memory. The first and second wires extend within the body and the first and second wings. In one aspect, the first and second wires extend within and are completely encapsulated within the body and the first and second wings. In one aspect, a conduit is provided within the body and the wings and the wires pass through the conduit. In one alternative, the conduit extends from the processor or electronic memory to an electrode so that the wire is completely within the conduit. In still other aspects of the devices described above, the first and second wires connecting the electrodes to the processor or electronics each include slack between the electrode and the processor. In one aspect, the slack is located in a portion of each wing that is configured to bed or flex. In another aspect, the slack is a portion of the wire within the wing and at least partially coiled about the first or the second electrode. In still other aspects, the slack is provided by a portion of the wire formed into a coil, a wave pattern, or a sinusoidal pattern along its length the connection point on the electronics to the connection point on the electrode.

In still other alternatives, the devices described above may be applied to any of a wide variety of conventional

physiological data monitoring, recording and/or transmitting devices. Any of the improved adhesion design features and aspects may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. Additional alternatives to the devices described may include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In still other aspects, the electronic component in any of the above devices is an electronic system configured for performing, with the electronic signals of the mammal detected by the electrodes, one or more or any combination of or the following electronic functions: monitoring, recording, analyzing, or processing using one or more algorithms electronic signals from the mammal. Still further, any of the devices described above may include appropriate components such that the device is used to detect, record, process or transmit signals or information related to signals generated by a mammal to which the device is attached including but not limited to signals generated by one or more of EKG, EEG and/or EMG.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

FIG. **1** is a top view of a patch having two wings;

FIG. **1**A is a representative cross-section of an embodiment of the patch in FIG. **1**;

FIG. **1**B is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**C is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**D is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**E is a representative cross-section of another embodiment of the patch in FIG. **1**;

FIG. **1**F is a top view of a patch having three wings illustrating an alternative electrode-electronics-electrode orientation;

FIG. **2**A is a schematic drawing of the electronics contained within a patch;

FIG. **2**B is a schematic drawing of a patch with wiring having slack in the form of undulations between electronics and electrodes;

FIG. **2**C is a schematic drawing of a patch with wiring having slack in the form of a coil between electronics and electrodes;

FIG. **3** is the bottom view of a patch having adhesive thereon;

FIG. **4**A shows a patch as worn by a person rolled to the side;

FIG. **4**B shows a patch as worn by a person playing golf;

FIG. **5**A shows a patch in response to a concave bend of the skin;

FIGS. **5**B and **5**C show a patch in response to a convex bend of the skin;

FIG. **6**A is a bottom view of a patch having a connector between two flaps;

FIG. **6**B is a cross-section of the patch of FIG. **6**A;

FIG. **7**A is a bottom view of a patch having multiple covers forming strips of adhesive;

FIG. **7**B is a cross-section of the patch of FIG. **7**A;

FIG. **8**A is a bottom view of a patching having multiple covers forming strip of adhesive around each electrode;

FIG. **8**B is a cross-section of the patch of FIG. **8**A;

FIGS. **9**A and **9**B show a patch having multiple layers formed thereon;

FIGS. **10**A and **10**B show a patching having multiple layers formed thereon, each layer having multiple patches of adhesive;

FIG. **11** shows a patch having an open cell support;

FIG. **12** shows a patch having an annular open cell support;

FIG. **13**A shows a patch having a protective shell thereon; and

FIG. **13**B shows a cross-section of the patch of FIG. **13**A.

DETAILED DESCRIPTION

The following device features and design elements can be implemented into any device being adhered to the human body for a long-period of time, typically greater than 24 hours. As an example, the following device features and design elements can be used for long-term adhesion of a cardiac rhythm monitoring patch ("patch") to the chest of a person.

Referring to FIGS. **1** and **1**A, a patch **100** for long term adhesion includes a housing **102**. The housing **102** can be formed from any flexible, durable material, such as a biocompatible polymer, for example silicone. The housing **102** can include electronic components **108** therein. As shown in FIG. **2**, the electronics **108** can include a printed circuit board **220**, a battery **225**, and a communications port mounted on the printed circuit board **220**. The printed circuit board **220** can include analog circuits **210**, digital circuits **215**, and an activation or event notation button or switch **130**. The electronics **108** can be used, for example, to record continuous physiological signals from a mammal wearing the patch **100**. A system for continuously recording data is described further in co-owned U.S. application Ser. No. 11/703,428, filed Feb. 6, 2007, the entire contents of which are incorporated by reference herein.

As shown in FIGS. **1** and **1**A, wings **104**, **106** can be connected to the housing **102**. The wings **104**, **106** can be integral with the housing **102** and, in some embodiments, can be formed of the same material as the housing **102**. The wings **104**, **106** can be more flexible than the electronic components **108**, which can be substantially rigid. An electrode **124**, **126** can extend through a bottom surface of each wing **104**, **106**. The electrodes can be positioned to detect an ECG of a mammal wearing the patch **100** for processing by the electronics **108**. For example, the electrodes can be more than 2 cm apart, such as more than 3 cm apart, for example at least 6 cm apart. The electrodes **124**, **126** can be integral with the wings **104**, **106** so as to be inseparable from the wings **104**, **106** when the patch is in use.

For a patch **100** that is entirely flexible and can conform, stretch, and adapt to the movement and conditions of the chest underneath the device, adhesive can be placed over the entire surface of the device that is in contact with the body, except for areas where sensors, electronics, or others elements such as electrodes are interacting with the body related to the functioning of the device may be incorporated.

Thus, as shown in FIG. **3**, an adhesive layer **166** can coat the bottom of the patch **100** for attachment to the skin, For a patch **100** in which there may be some areas that are not completely flexible and may not be able to stretch or contract (e.g., the electronics **1**(**8**), adhesive may be excluded from the portion of the patch **100** underneath these areas. Thus, for example, the bottom surface **302** of the housing **102**, which contains the electronics, can remain free from adhesive. As shown in FIG. **1** A, by not coating adhesive on a bottom surface of the housing **102**, the housing **102** can float above the adhered portions, allowing for increased flexibility of the patch, as will be discussed further below. Further, as shown in FIG. **3** the bottom surface of the electrodes **124**, **126** can remain free of adhesive. For example, a ring **362** without adhesive can be formed around each electrode **124**, **126** to separate the electrodes from the adhesive **164**, The adhesive can be, for example, a pressure-sensitive adhesive, such as polyacrylate, polyisobutlene, or a polysiloxane. Alternatively, the adhesive can be a hydrocolloid which advantageously absorbs water.

The wings **104**, **106** and the housing **102** can form a smooth, contiguous outer surface to the patch **100**, As shown in FIG. **1** A, when viewed from the top, the housing **102** and wings **104**, **106** can together form an oblong substantially oval shape, Further, the housing **102** can have a thickness that is greater than the thickness of the wings **104**, **106**. The housing **102** and each of the wings **104**, **106** when viewed in profile, can each form a dome with a height that is greater at the center than at the ends of the respective component, i.e. some or all of the components can be tapered at the ends and/or sides.

The electronics **108** can extend along only a portion of the distance between the electrodes **104**, **106**. For example, the electronics can occupy less than 90% of the distance between the electrodes, for example less than 80%. By having the electronics **108** in a relatively limited space between the electrodes **124**, **126**, the flexibility of the patch **100** can be increased

The housing **102** can provide a watertight enclosure **110** for electronic components **108** of the patch **100**, The electronics **108** can be unattached to the housing **102** such that the electronics **108** are free to move within the watertight enclosure **110**. Allowing the relatively rigid electronics **108** to move freely within the flexible housing **102** advantageously enhances the overall flexibility of the patch **100**, The wings **104**, **106** can each have a watertight enclosure **114**, **116** formed therein, which can be contiguous with the watertight enclosure **110** of the housing **102**.

Wiring **120** or other suitable electrical connections can connect the electrodes **124**, **126** with the electrical components **108** of the housing. In some embodiments, as shown in FIGS. 1B-IE, the contiguous nature of the enclosure **110** and the enclosures **114**, **116** allows the wiring **120** to extend within the patch **100** from the electrodes **124**, **126** to the electronic components **108**. In other embodiments, one or more channels, tubes, or conduits are provided between the housing **102** and the wings **104**, **106**, to provide space for the wiring **120**. The tube or channel may be straight or curved. In use, the wire **120** positioned in the enclosures **110**, **114**, **116** or in the tube or channel may move relative thereto in order to remain flexible within the housing. In one aspect, the flexible channels or tubes are formed within the device housing so that the housing, as it is being stretched, does not affect the ability of the components, such as wires, that may connect more rigid structures, to move or elongate.

As shown in FIG. **1**, the wire **120** is straight with a direct line of connection between the electrodes **124**, **126** and the

electronics **108**. FIG. **1** illustrates an embodiment where the length of the wires **120** connecting the electrodes **124**, **126** to electronics **108** are about the same distance as the spacing between the electrode connection point on electronics **108** and the electrodes **124**, **126**. FIG. **1**F also illustrates a straight line type connection where wire **120** length is nearly the same as the spacing between the electronics **108** and the electrodes **124**, **126**. However, as a patient moves, the patch **100** flexes along with patient movement. As shown in FIGS. **4**B and **5**C, patch flexion may be severe and is likely to occur during long term monitoring. In order to address the possible dislocation or breakage of the wire **120**, the length or shape of the wire **120** may be selected to permit patch flexion to occur with little risk of wire **120** pulling from the electrode or electronics. Numerous alternatives are possible to compensate for patch flexion. Exemplary confirmations include undulations or zig-zags **231** as shown in FIG. **2**B, coils **233** as shown in FIG. **2***e*, or a configuration that partially or fully wraps around an electrode. In some embodiments, other components, such as the circuit hoard or electrodes, can alternatively or additionally contain additional length to help accommodate stretch or displacement. When the patch **100** is attached to a mammal, the slack in the wiring **120** allows the patch **100** to flex while not placing stress on the wiring **120**.

While the illustrated embodiments of FIGS. **1**A-**1**D show only two wings and show the electrodes and electronics in a direct line in a approximate 180 degree alignment of electrode **124** to electronics **108** to electrode **126**), other configurations are possible. For example, as shown in FIG. **1**F, the wings **104**, **106** are arranged in an orientation less than 180 degrees. In the illustrated embodiment, the angle formed by the electrodes and the electronics is about 135 degrees. Other ranges are possible so long as electrode spacing is provided to permit ECG monitoring. The orientation of the wings **104**, **106** to the housing **102** also illustrates the use of an additional adhesive tab **105**. Tab **105** is shown as a semicircular extension of the body **102**. The bottom of tab **105** can include adhesives as described herein and is used to provide additional anchoring of the patch to the patient. The tab **105** may be formed in any of a number of different shapes such as rectangles, ovals, loops or strips. Further, in some embodiments, the tab **105** can function similar to a wing, e.g., include an electrode therethrough that connects to the electronics **108**.

Referring to FIGS. **1**A-**1**D and **2**B-**2**C, a hinge portion **194**,**196** in the patch **100** can extend between each electrode **124**, **126** and the electronics **108**. The hinge portions **194**, **196** can have a thickness less than the thickness of surrounding portions of the patch **100**, For example, if the hinge portions **194**, **196** are in the wings **104**, **106**, then the thickness can be less than adjacent portions of the wings. Likewise, the hinge portions **194**, **196** can have a width less than adjacent portions of the patch **100**, e.g., less than adjacent portions of the wings **104**, **106**. Alternatively, the hinged portion can be formed by the adjunct between a rigid portion, i.e. the electronics **108**, and a more flexible portion, The hinged portion allows the patch **100** to bend between the housing **102** and wings **104**, **106** to compensate for any movement caused by the patient. As shown in FIGS. **2**B and **2**C, the slack in the wiring **120** can be placed at or proximal to the hinge portions **194**, **196** to allow for bending at the hinge portions **194**, **196** without pulling or breaking the wiring **120**.

Referring to FIGS. **4**A and **4**B, having adhesive on the bottom of the patch **100** except in the areas substantially around the electrodes and directly underneath the housing

102 can create a floating section **455** over the skin of the mammal to which the patch **100** is attached. The floating section **455** can house the more rigid or less flexible electronic components while the flexible wings **104**, **106** can be adhered to the skin and provide the flexibility necessary to hold the patch **100** in place. As a result of this selective use of adhesive areas and non-adhesive areas, the limitation on device flexibility imposed by the less flexible floating section can be mitigated or reduced by hounding the floating section with one or more adhered flexible areas. The flexible sections can thus adhere to the body if the underlying portion of the body is stretched and/or contracted while the floating section is free to move above the skin, for example if the person wearing the device rolls over (as shown in FIG. **4**A) or is involved in activities that can otherwise cause movement of the skin (as shown in FIG. **4**B).

Referring back to FIGS. **1**B-**1**E, each wing **104**, **106** can include a material layer **214**,**216** between the adhesive **164**, **166** and the wings **104**, **106**, The material layer **214**,**216** can be, for example, a polyester layer. The material layer **214**, **216** can be attached to the patch **100** with a layer of adhesive **204**,**206**, The adhesive **204**, **206** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **204**, **206** could be a silicone adhesive. The material layer **214** can serve as a barrier to prevent diffusion or migration of adhesive components, such as a tackifier, from the adhesive **164**, **166** into the wings **104**, **106** or housing **102**. The material layer **214** can thus advantageously serve to maintain the strength of the adhesive **104**, **106** over time.

Referring still to FIGS. **1**B-IE, the patch **100** can further include a first flap **154** connected to the first wing **104** and a second flap **156** connected to the second wing **106**. The flaps **154**, **156** can both extend from a position on the wings **104**, **106** medial to the electrodes to a position below the housing **102**, such as below the electronics **108**. The flaps **154**, **156** can remain unattached to the housing **102**. As a result, gaps **144**, **146** can be formed between the flaps **154**, **156** and the housing **102**. The gaps can provide additional “floating” for the housing **102** and the relatively rigid components **108** contained therein.

In some embodiments, shown in FIG. **1**B, the flaps **154**, **156** can be attached to the wings **104**, **106** with adhesive **134**, **136**. The adhesive **134**, **136** can be the same as the adhesive **164**, **166** or different. For example, the adhesive **134**, **136** could be a silicone adhesive. In other embodiments, shown in FIGS. **1**C-IE, the flaps **154**, **156** can be integral with the wings **104**, **106**. For example, the flaps **154**, **156** can be solvent welded to and/or formed during the molding process of the wings **104**, **105** such that hinges **194**, **196** form below the wings **104**, **106**. Additionally or alternatively, one or more of the flaps **154**, **156** may be separably attached to the wings **104**, **106**. In some embodiments, shown in FIGS. **1**B and **1**C, the materials making up the flaps **154**, **156** can extend all the way to the lateral edge of the patch **100**. In other embodiments, shown in FIG. **1**D, a flap can extend on each side of the electrodes, i.e. one flap can extend medially and the other laterally. In some embodiments, the lateral and medial-extending flaps are part of the same annular flap. In other embodiments, shown in FIG. **1**E, the flaps and materials making up the flaps extend only from a position medial to the electrodes underneath the housing.

The Flaps **154**, **156** may be positioned in virtually any relationship to the adhered flexible area such that, when attached in use, the attachment of the flap or flaps effectively counteracts the expected external forces acting on the device, specifically those forces that may dislodge the adhered flexible areas. Further, in embodiments such as that

shown in FIG. 1F where there are more than two wings, there can be a flap corresponding to each additional wing.

The adhesive layers **164**, **166** can coat all or a portion of the bottom of each of the flaps **154**, **156**. In some embodiments, the adhesive **164**, **166** extends continuously from the bottom surface of the wings **104**, **106** to the bottom surface of the flaps **154**, **156**, except for areas proximate to the electrodes **124**, **126**. Further, the top surface of the flaps **154**, **156**, i.e. the surface closest to the housing **102**, can remain free of adhesive to ensure that the housing **102** remains floating. In some embodiments, the only portion of the patch **100** including adhesive for adhesion to the skin can be the flaps **154**, **156**.

Referring to FIGS. **5**A-**5**C, the naps **154**, **156**, can provide hinge-like behavior for the patch **100**, Thus, as shown in FIG. **5**A, if the skin **501** is stretched or bent in a concave manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can approach zero such that the patch **100** can sit substantially flat on the skin **501**. As shown, the hinge portions **194**, **196** between the housing **102** and wings **104**, **106** can provide additional flexibility for concave bends by flattening as the patch **100** is stretched. In contrast, as shown in FIGS. **5**B and **5**C, as the skin **501** is bent in an increasingly convex manner, the gaps **144**, **146** between the flaps **154**, **156** and the housing **102** can increase, thereby allowing the flexible wings **104**, **106** to remain adhered to the skin and the rigid housing **102** to float above skin. As shown, the hinge portions **194**, **196** between the housing and the wings **104**, **106** can provide additional flexibility for convex bends by folding inward as the patch **100** is bent.

When placed substantially flat on the skin **501**, the patch **100** can have a height that extends no more than 2 cm off of the skin, such as no more than 1.5 cm off of the skin, when lying flat on the patient and no more than 4 cm, such as no more than cm off of the skin when floating above the skin. The relatively low height of the patch **100** can enhance long-term adhesion by reducing the potential for the patch] **00** to snag or rip off of the skin.

Advantageously, the flaps **154**, **156** can function as anchors for adhesion that mitigates shear force. The flaps **154**, **156** can provide a different direction for the acute and chronic forces being experienced by the device due to stretching, contraction, or torsion to be spread out over both the flap as well as the flexible adhesive areas. Further, by pre-aligning the orientation of the floating section, adhered flexible area and the flaps, the device may be better able to tolerate (i.e., remain attached to the body and in use) and/or tailor the interaction with the forces acting on the device in order to better withstand the acute or chronic forces being experienced by the device. Tailoring the response of the device to the expected forces is one

Because the flaps can be used to counteract forces acting on a particular device, it is to be appreciated that the dimensions, flexibility, attachment technique, and/or orientation between a flap and another component may vary depending upon the purpose of a particular flap. Accordingly, a flap may have the same or different characteristics from another flap or component of the device. In one aspect, at least one flap is more flexible that the other flaps in a particular device. In another aspect, each of the flaps has similar flexibility. In still another aspect, at least one flap is more flexible than the device component to which it is attached or from which it originates. In still another aspect, at least one flap is less flexible than the device component to which it is attached or from which it originates.

Referring to FIGS. **6**A and **6**B, in one embodiment, the flaps **154**, **156** may be augmented by a connector segment

607 used to join the flaps together. The connector segment **607** can extend below the housing **102**, but remain unattached to the housing **102**. As shown in FIG. **6**A, the flaps **154**, **156** and the connector **607** can together form a butterfly shape. In one embodiment, the connector segment **607** and the flaps **154**, **156** are formed from a single piece of material. The connector segment **607** can be made of the same material as the flaps **154**, **156** or of different material. In one embodiment, the bottom surface of the connector is covered with adhesive. In another embodiment, the bottom surface of the connector does not include any adhesive. Further, as shown in FIG. **6**B, the connector segment **607** can be thicker in the middle, under the housing **102**, than near the edges, i.e., closer to the electrodes. The variable thickness can help prevent the connector segment **607** from capturing moisture thereunder. The connector segment **607** can advantageously prevent the device from flipping when attached to the patient

The connector segment **607** can include one or more holes **614**, **616**. In some configurations, the connector segment may trap moisture and/or inadvertently stick to the body. The holes **614**, **616** can advantageously minimize the potential for undesired sticking or moisture collection. The size, shape and placement of the holes mitigate or reduce the collection of moisture and/or undesired adhesive still providing a connector with sufficient structural integrity (i.e. the connector allows the flaps to be connected to one another in order to prevent them from folding). Additionally or alternatively, the connector holes could also be made to preferentially allow forces to be distributed along certain axes of the connector in order to further maximize the ability of the device to adhere tong-term in the face of significant acute and chronic forces due to stretching, contraction, and torsion.

Adhesive can be selectively applied to the connector and/or naps to provide the desired body attachment locations depending upon the specific use of the device. For example, one piece of material including flaps and the connector can be adhered along two or more edges and/or with adhesive only covering certain areas, In another aspect, at least a portion of the skin-contacting surface of the unitary nap connector structure does not include any adhesive. Additionally or alternatively, the connector segment incorporating the flaps may be integral parts of the larger device housing (e.g. could be molded as part of the device housing or enclosure).

In some embodiments, the patch **100** can include one or more release liners to cover parts of the adhesive prior to adhesion. As is particular to devices having multiple adhesive areas and/or multiple adhesive components (i.e., flaps and flexible sections), the manner of applying the device may be specifically detailed in order to ensure that the device and the adhesive portions are properly engaged. In one particular aspect, the release liners are removed in a particular order to minimize the likelihood that the device adhesive is misapplied. For example, a portion of the adhesive may be exposed first and used to affix the device to the body, Thereafter, a second set of adhesive liners may be removed to expose and affix one or more flaps to the body, A stepwise adhesive exposure method may be implemented during device application such that elements, such as the one or more flaps do not fold on themselves, for example.

Breaking up the areas in which the adhesive is used to adhere the device, whether it be splitting it up to rigid areas, to create flaps, to create connector segments with holes, of any of the other techniques described above may also have benefits in terms of preventing moisture bridges that could act as conducting pathways between electrical sensing ele-

ments, such as electrodes. Bridges of moisture could short-circuit electrical connections and/or prevent the proper functioning of the device, particularly if the device has an electrical function, such as sensing via electrodes.

In some applications, a long-duration patch may experience excessive forces due to acute (quick and/or rapid) or chronic (slow and/or prolonged) contraction, stretching, or torsion. In such applications, the hinge points between a floating rigid section and flexible adhered sections may be modified in order to align with and counteract or mitigate the predominant direction of the force acting on the patch. In some device situations or configurations, the strength and direction of the acute or chronic force may be so strong that the forces imparted on the device adhesive surfaces or components may be distributed differently in addition to or as an alternative to the hinge described above.

Further, the device construction can be made in such a way that the housing is fashioned so that the axes of the housing are structured and placed along or against the direction of various forces, possibly during certain states, such as sleeping, so that the device itself can help counteract these forces and improve long-term adhesion.

Advantageously, the patch described herein can provide long-term adhesion to the skin. Having the various flexible portions and/or hinged portions can compensate for stressed caused as the skin stretches or bends, while allowing the rigid portion to float about the skin. As a result, the devices described herein can adhere to the skin substantially continuously tor more than 24 hours, such as greater than 3 days, for example, greater than 7 days, greater than 14 days, or greater than 21 days.

Another mechanism for adhering a patch to the skin long-term is described with respect to FIGS. **7-10**. As shown in the embodiments of FIGS. **7-10**, one or more parts of the patch are used in a temporary fashion in order to improve adhesion. The adhesive used in the embodiments described below can include a hydrocolloid or a pressure-sensitive adhesive, such as polyacrylate, polyisobutylenes, or polysiloxane.

In one embodiment, shown in FIGS. **7**A and **7**B, the patch **700** can be surrounded with an adhesive **760** having multiple covers **701**, **703**, **705** thereon that can be peeled away in a sequence to expose strips of adhesive **760** underneath. The covers **701**,**703**,**705** can be concentric with one another and be configured to be pulled off separately and sequentially starting from the inside of the patch **700**. Each additional exposed area of adhesive **760** can increase the adhesion life of the patch **700**. Although only three covers are shown in FIG. **7** A, other numbers, such as 2, 4, 5, or more are possible. Further, each electrode **124**, **126** of the patch **700** can include a barrier **714**,**716** to protect the electrodes **124**, **126** from shortage.

In another embodiment, shown in FIGS. **8**A and **8**B, each electrode **124**, **126** can be surrounded by a patch of adhesive **864**, **866**. Accordingly, a set of covers **801**, **803**, **805**, **807** can be positioned sequentially around each of the electrodes **124**, **126** over the adhesive **864**, **866**. The covers **801**, **803**, **805**, **807** can be concentric with one another and be configured to be pulled off sequentially starting from the inside. Each additional exposed strip of adhesive **864**, **866** can increase the adhesion life of the patch **100**. Although only four covers are shown in FIG. **8**A, other numbers, such as 2, 3, 5, or more are possible. Further, each electrode **124**, **126** of the patch **800** can include a barrier **814**, **816** to protect from shortage.

Referring to FIGS. **9**A-**9**B, in other embodiments, shells or layers **901**,**902**,**903** can extend over all or a portion of the patch **900**. Each layer **901**,**902**,**903** can include a strip of adhesive **962** on the bottom surface and an adhesion guard **982** protecting the adhesive. As shown in FIG. **913**, as the patch **900** is worn over a period of time, the layers **901**, **902**, **903** can be sequentially removed. As a new layer is exposed, the adhesive guard **982** of that layer can be peeled away such that the adhesive **962** of the new layer can be used to adhere the patch **900** to the skin, In a similar embodiment, referring to FIGS. **10**A-**10**B, each of the layers **1001**, **1002**, **1003** can include multiple portions of adhesive to help adhere the layer to both the skin and the patch itself. As with the embodiments of FIGS. **7-8**, the number of layers in the embodiments of FIGS. **9** and **10** can vary. For example, there can be 2, 3, 4, or 5 or more layers.

In some embodiments, the layers or covers of the embodiments described herein can be added to the device over time to improve adhesion. Further, the multiple layers or covers of the embodiments described herein can be partially overlapped. Further, in some embodiments, the strips of adhesive can be overlapped.

Advantageously, the use of multiple covers or layers can assist in the adhesive performance of a base or core device because the added surface area or adhesive force of the combined outer layer aids in preventing layer pull away and/or may act to spread forces being experienced away from the core device by spreading those forces over a larger area.

Referring to FIGS. **11** and **12**, an open cell structured support **1330** or porous foam can be used to support a more rigid or less flexible portion **1302** of the patch **1300**, As shown in FIG. **11**, the open cell structured support **1330** can fully fill an area below the rigid portion **1302**. Alternatively, as shown in FIG. **12**, the open cell structured support **1330** can be an annular shape or have some other configuration that includes spaces between adjacent portions of the support. The open cell structured support **1302** may be attached to both the skin and to the rigid portion, to only the rigid portion, or to only the skin. Because of the open cell structure of the support, the flexible movement of the skin can be absorbed by the structure entirely or partially such that the rigid portion does not impact or has a reduced impact on the ability of the device to accommodate movement and remain affixed. In addition, the open cell support may have a thickness selected to enhance patient comfort so that the more rigid portion of a device does not push against the skin. In one aspect, the open cell structure is a biocompatible foam material. In another aspect, the open cell material is positioned between an electronics module on the device and the skin when worn by a patient. The open cell support can advantageously absorb fluids to keep the electrodes from shorting.

Referring to FIG. **13**, the patch can have a shell design. Adhesive can be placed on the perimeter edge of the bottom ring. The circuit board and electrode unit can be dropped into the bottom ring, and a shell can be dropped on top of the circuit board and electrode. The perimeter adhesive can create a watertight chamber therein.

The shape of a particular electronic device embodiment may vary. The shape, footprint, perimeter or boundary of the device may be a circle or circular (see FIG. **13**A), an oval (see FIG. **1**A, **2**A), a triangle or generally triangular (see FIG. **1**F) or a compound curve. Examples of a device embodiments having a compound curve shape are shown in FIGS. **2**B, **2**B, **3**, **6**A, **7**A, and **8**A. In some embodiments, the compound curve includes one or more concave curves and one or more convex curves. FIG. **3** illustrates a device having a convex surface along the top (where reference **102**

indicates), a concave surface along the bottom and convex shaped edges around the electrodes **124**, **126**. FIGS. **2**B and **2**C illustrate a device embodiment having a convex shape on either side of the electronics **108** and around the electrodes **124**, **126**. The convex shapes are separated by a concave portion. The concave portion is between the convex portion on the electronics and the convex portion on the electrodes, In some embodiments, the concave portion corresponds at least partially with a hinge, hinge region or area of reduced.

While described in the context of a heart monitor, the device adhesion improvements described herein are not so limited. The improvement described in this application may be applied to any of a wide variety of conventional physiological data monitoring, recording and/or transmitting devices. The improved adhesion design features may also be applied to conventional devices useful in the electronically controlled and/or time released delivery of pharmacological agents or blood testing, such as glucose monitors or other blood testing devices. As such, the description, characteristics and functionality of the components described herein may be modified as needed to include the specific components of a particular application such as electronics, antenna, power supplies or charging connections, data ports or connections for down loading or off loading information from the device, adding or offloading fluids from the device, monitoring or sensing elements such as electrodes, probes or sensors or any other component or components needed in the device specific function. In addition or alternatively, devices described herein may be used to detect, record, or transmit signals or information related to signals generated by a body including but not limited to one or more of EKG, EEG, and/or EMG.

What is claimed is:

1. An electronic device for long-term adhesion to a user, the device comprising:

a housing comprising a physiologic data collection circuit, the housing positioned over a flexible layer extending from beneath the housing, the flexible layer comprising an electrode positioned on the bottom of the flexible layer at a position distal from the housing, wherein the flexible layer comprises a polymer upper layer overlying an electrical connection, the electrical connection extending linearly from the physiologic data collection circuit to the electrode when viewed from above the electronic device, the polymer upper layer adhered to a polymer lower layer underlying the electrical connection;

a connecting adhesive layer positioned under the polymer upper layer, the connecting adhesive layer adhering the polymer upper layer to the polymer lower layer; and

a lower adhesive layer positioned on the flexible layer and configured to adhere the electronic device to a user.

2. The electronic device of claim **1**, further comprising a flap extending beneath the housing.

3. The electronic device of claim **1**, wherein the housing is rigid.

4. The electronic device of claim **1**, wherein the housing is configured to remain connected to the flexible layer when the housing is tilted at an angle relative the lower adhesive layer in response to movement of the user.

5. The electronic device of claim **1**, further comprising a hinge portion adjacent the housing.

6. The electronic device of claim **1**, wherein the lower adhesive layer comprises a hydrocolloid adhesive.

7. The electronic device of claim **1**, wherein the physiologic data collection circuit is configured to collect cardiac rhythm data from the user.

8. The electronic device of claim **1**, wherein the polymer upper layer extends horizontally away from the housing beyond a boundary of the electrode.

9. The electronic device of claim **1**, further comprising an upper adhesive layer positioned over the polymer upper layer.

10. The electronic device of claim **9**, wherein the upper adhesive layer is positioned above the electrode.

11. The electronic device of claim **10**, wherein the upper adhesive layer extends horizontally away from the housing beyond a boundary of the polymer upper layer.

12. The electronic device of claim **1**, wherein the lower adhesive layer extends at least partially below the housing.

13. The electronic device of claim **1**, wherein the lower adhesive layer does not extend below the housing.

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